K012430

BIONOSTICS

AUG 2 7 2001

510(k) Summary[*]

(a) (1) **Submitter's name, address**
Bionostics, Inc.
2 Craig Road
Acton, MA 10720

Contact Person
Kathleen Storro
Director, QA & Regulatory Affairs
(978) 263-3856 x 220

Date of preparation of this summary: 27 July 2001

(2) **Device trade or proprietary name:** **Multi-Meter Glucose Calibration Verification Material**

Device common or usual name or classification name:

Multi Analyte Control Solution, All Types (Assayed and Unassayed)

PRODUCT NOMENCLATURE	CLASSIFICATION NUMBER	CLASS	PANEL
SINGLE ANALYTE CONTROL SOLUTION	862.1660 75 JJX	I	CHEMISTRY

(3) **Substantial Equivalence**
Multi Analyte Glucose Calibration Verification Material is substantially equivalent in function, safety and efficacy to currently marketed devices produced by Bionostics. In example:

Comparison of Multi-Meter Glucose Calibration Verification Material to predicate devices for substantial equivalency

Characteristic	Predicate Devices		Modified Device
Name:	Sugar Chex Linearity for One Touch	Quality Control Solution for MediSense BGM	Multi-Meter Glucose Calibration Verification Material
510(k), Date:	K925479, 01/29/93	K002540, 09/18/2000	
Number of levels:	5	5	5
Analytes:	Glucose	Glucose	Glucose
Container:	plastic bottle	plastic bottle	plastic bottle
Fill volume:	2 mL	4 mL	4 mL
Color:	red	red	red
Matrix:	Stabilized human red blood cells with glucose in a medium with perservatives.	Buffered, aqueous solution of D-Glucose, viscosity modifier, preservatives and other, non-reactive ingredients.	Buffered, aqueous solution of D-Glucose, viscosity modifier, preservatives and other, non-reactive ingredients.

[*] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

(4) **Description of the new device**
Multi-Meter Glucose Calibration Verification Material is a five-level, viscosity-adjusted, aqueous liquid glucose control linearity set. **Multi-Meter Glucose Calibration Verification Material** provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a red color to help users see the solution while dispensing onto a test strip.

Multi-Meter Glucose Calibration Verification Material contains glucose values at the lower and upper limits of reportable range as well as three points within the range and therefore, may be used to assess the linearity and calibration, or verify performance, for each of a number of blood glucose meters listed on the package insert.

Multi-Meter Glucose Calibration Verification Material is a non-hazardous aqueous solution containing no biological materials.

(5) **Intended use of the device**
Multi-Meter Glucose Calibration Verification Material is intended to be used to monitor and evaluate the analytical performance of a number of popular blood glucose meters (BGM) as listed in the package insert..

(6) **Technological characteristics of the device.**
This material consists of viscosity-adjusted, aqueous glucose control solutions prepared in five specific glucose concentrations. The solutions have been optimized to simulate the response of whole blood on a number of blood glucose meters listed in the package insert.

(b) (1) **Summary of non-clinical tests submitted with the premarket notification for the device.**
Tests were conducted to verify specific performance requirements:

a) Accelerated aging studies on most labile analytes, together with experience with other products with similar formulations support stability claim.

b) Test precision

c) Correlation to reference methodology

(b) (2) **Summary of clinical tests submitted with the premarket notification for the device.**
N/A

(b) (3) **Conclusions drawn from the clinical and non-clinical trials.**
Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 7 2001

Ms. Kathleen Storro
Director, QA and Regulatory Affairs
Bionostics, Inc.
2 Craig Road
Acton, MA 01720

Re: K012430
Trade/Device Name: Multi-Meter Glucose Calibration Verification Material
Regulation Number: 21 CFR 862.1660
Regulatory Class: I, reserved
Product Code: JJX
Dated: July 27, 2001
Received: July 31, 2001

Dear Ms. Storro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012430

Device Name: **Multi-Meter Glucose Calibration Verification Material**

Indications for Use:

Multi-Meter Glucose Calibration Verification Material assayed controls are intended for use to verify the performance of multiple blood glucose meters as indicated on the package insert at their upper and lower ends of reportable range and at three points within the range. These controls can therefore be used to assess the linearity and calibration of the test system, or to verify the test systems' performance.

For *In Vitro* Diagnostic Use

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Kesia Alexander for: Jean Cooper (Optional Format 1-2-96)
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012430